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EXAMINER	
MOORE, SUSANNA	
ART UNIT	PAPER NUMBER
1624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/500,040	EGGENWEILER ET AL.	
	Examiner	Art Unit	
	Susanna Moore	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-23 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6-23-2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Objections

Claims 10 and 11 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 21 is objected to because of the following informalities: Markush claims should be written in the alternative. Appropriate correction is required.

35 U.S.C. 112 - Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-9, 13, 14-20, 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14-20 provides for the use of compounds, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is

intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Regarding claims 1-9 and 13, 22 and 23 the phrase "derivatives" renders the claim indefinite because it is unclear what Applicant means by "derivatives."

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 11-15 and 22-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-9, 11-15 and 22-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for other forms, does not reasonably provide enablement for solvates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims 1-9, 11-15, 22 and 23 are drawn to solvates. But the numerous examples presented all failed to produce a solvate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 "The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist." The same circumstance appears to be true here: there is no evidence that solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

35 U.S.C. 101 - Rejections

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims14-20 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

35 U.S.C. 102 - Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 6, 7, 10, 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Missbach et. al. (U.S. 5,869,485).

Missbach discloses substituted pyrrolopyrimidines as tyrosine protein kinase inhibitors. The specie labeled as example 2, in column 16, line 6 in the reference, provides a corresponding to R5= NH2, X= phenyl, R6= hydrogen, R3= methyl and R4= phenyl in the claims. The reference also teaches a specie wherein R5= NH2, X= phenyl, R3=chloro, R4= phenyl, and R6= hydrogen

in the claims. See example 31, column 26, lines 51-54 of the reference. The referenced invention also teaches pharmaceutical compositions, see column 13, starting at line 35 of the reference.

Claims 1, 5, 7 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et. al. (U.S. Patent 6,765,008).

Chen et. al. discloses substituted pyrrolopyrimidines as corticotropin-releasing factor antagonists. The specie in column 15, lines 52-55 in the reference, provides a compound corresponding to R5= n-butyl ethyl amine, X= trimethyl phenyl, R6= hydrogen and R3 and R4= methyl in the claims. The synthesis of these compounds is found in columns 7 and 8 (bridged) of the reference. The synthesis incorporates compounds of formula (V) reacted with the appropriate nucleophile to obtain the corresponding compounds of formula (I). Also, the reference teaches compositions, see column 10, starting at line 23 of the reference. The compositions read on claim 13 of the current invention.

Claims 1-3, 5-7, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Klumpp et. al. (Biochemical. Pharmacology, 1989, 38(6), 949-953).

Klumpp teaches structure-activity relationships of pyrrolopyrmidines as inhibitors of cAMP-Phosphodiesterase. For example, compound 3 in the reference provides a compound corresponding to R5= OH, R6= hydrogen, X= phenyl, and R3 and R4= methyl group in the claims. See table 1, page 951 of the reference. Also, note compound 6 in the reference, wherein R5= NH2, R6= NH2, X= phenyl and R3 and R4= methyl in the claims. And compound 12, where the variables are R6= hydrogen, R5= NH2, X= p-chlorophenyl and R3 and R4= methyl.

The compounds mentioned herein are just a few of the compounds in table 1 on page 951, although most of the compounds in table 1 meet the limitations of claims 1-3, 5-7, 10 and 11. And as so, are anticipated by Klumpp et. al.

Claims 1-3, 5-7, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Daly et. al. (Biochemical. Pharmacology, 1988, 37(19), 3749-3753).

Daly teaches substituted pyrrolopyrmidines as adenosine receptor antagonists. For instance, compound 18 in the reference provides compounds corresponding to R5= OH, R6= hydrogen, X= o-chlorophenyl, and R3 and R4= methyl group in the claims. See table 1, page 3752 of the reference. Also, see compound 6, wherein R5= NH2, R6= NH2, X= m-methoxyphenyl and R3 and R4= methyl in the claims. Here again, the compounds mentioned are just a few of the compounds in table 1 on page 3752 of the reference while most of the compounds in table 1 meet the limitations of claims 1-3, 5-7, 10 and 11, and as so, are anticipated by Daly et. al.

Claims 1-3, 5-7 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Roth et. al. (U.S. 4,229,453).

Roth et. al. teaches substituted pyrrolopyrmidines as agents to treat CNS disorders or inflammatory diseases. For instance, example 1 in the reference, wherein R5= NH2, R6= hydrogen, X= 4-chlorophenyl, and R3 and R4= methyl group. See column 6, lines 57-58 of the reference. Also, see example 14, column 8, line 56-57 of the reference, wherein R5= hydroxy, R6= hydrogen, X= phenyl and R3 and R4= methyl. Here again, the compounds mentioned are just

a few of the compounds found in said reference that meet the limitations of said claims, and as so, are anticipated by Roth et. al. The synthesis incorporates compounds of formula (II) reacted with the appropriate carboxylic acid to obtain the corresponding compounds of formula (I) as shown in column 2 of the reference. The synthesis reads on claim 12. Also, said invention teaches medicaments, see column 4, starting at line 19 and columns 5 and (bridged) of the reference.

Claims 1, 5, 7, and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Eger et. al. (DE 31 45 287).

Eger et. al. teaches substituted pyrrolopyrmidines as agents to treat CNS disorders. For instance, example 7 in the reference, wherein R5= OCH2CH3, R6= hydrogen, X= phenyl, and R3 and R4= methyl group. See page 10 of the reference and claims 1, 5-7, 10 and 11. Here again, the compounds mentioned are just a few of the compounds found in said reference that meet the limitations of claims 1, 5-7, 10 and 11, and as so, are anticipated by Eger et. al. The reference also teaches the synthesis shown on page 6, reaction scheme 1. The synthesis incorporates compounds of formula (II) reacted with the appropriate carboxylic acid to obtain the corresponding compounds of formula (I) as shown in column 2. The reaction scheme also shows the substitution of the 4-chloro pyrrolopyrimidine with a nucleophile to produce the corresponding 4-substituted pyrrolopyrimidines. Lastly, the reference teaches medicaments, see page 11 and claim 13. The medicaments read on claim 13.

Claims 1, 5-7, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyashita et. al. (Heterocycles, 1994, 39(1), 345-356).

Miyashita teaches the preparation of substituted pyrrolopyrmidines. For example, compound 10a of the reference provides an anologue corresponding to R5= Cl, R6= hydrogen, X= phenyl, and R3 and R4= methyl group in the claims. See page 348 of the reference and claims 1, 5-7, 10 and 11 of the current invention. Also, note compound 20a of the reference, wherein R5= CN, R6= H, X= phenyl and R3 and R4= methyl. Compounds 10 a and 20a of the reference meet the limitations of the claims mentioned above, and as a result, are anticipated by Miyashita et. al.

Claims 1-3, 5-7, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Steinhilber et. al. (Pharmaceutical Research, 1986, 3, 271-277).

Steinhilber teaches substituted pyrrolopyrmidines as 5-lipoxygenase inhibitors. Compound 12 in the reference provides an anologue wherein R5= NH2, R6= hydrogen, X= phenyl, R3= CH2OH and R4= methyl group. See page 274, table II in the reference. Also, note compound 15 in the reference, wherein R5= NH2, R6= NH2, X= phenyl and R3 and R4= methyl. Another example is compound 19 where R5= OH, R6= hydrogen, X= phenyl, R3= NO2 and R4= methyl. These examples meet the limitations of claims 1-3, 5-7, 10 and 11, and as so, are anticipated by Steinhilber et. al.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Abdelhamid et. al. (Heterocycles, 1988, 27(8), 1861-1866).

Abdelhamid teaches the synthesis of substituted pyrrolopyrmidines with heterocyclic enaminonitriles. Compound 2 on page 1862 of the reference; wherein X= p-methyl phenyl, R3=

ethyl ester, R4= methyl, is heated with formic acid which provides the corresponding pyrrolopyrmidine, compound 7, wherein R6= hydrogen and R5= OH. The reaction proceeds with formic acid to give the corresponding pyrrolopyrimidine, with R6= hydrogen and R5= OH. These examples meet the limitations of claims 1-12, and as so, are anticipated by Abdelhamid et. al.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Eger et. al. (J. Heterocyclic Chem. 1987, 24, 425-430).

Eger teaches the synthesis of substituted pyrrolopyrmidines with o-aminonitriles. Compound 11a on page 426 in the reference provides an analogue, wherein X= phenyl, R3= methyl, R4= methyl, R5= SCH3 and R6= SCH3. Further oxidation of this compound gave compound 12a, wherein X= phenyl, R3= methyl, R4= methyl, R5= SO2CH3 and R6= SO2CH3. These examples meet the limitations of claim 1, and as result, are anticipated by Eger et. al.

35 U.S.C. 103 - Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 3, 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et. al. (see above reference).

The current invention teaches substituted pyrrolopyrimidines of formula (I), wherein X= substituted phenyl; R3= methyl and R6= hydrogen.

Chen et. al. teaches substituted pyrrolopyrimidines of Applicants formula (I), wherein X= di- and trisubstituted phenyl, R3= hydrogen and R6= methyl.

The difference between the current invention and the reference is the level of substitution on the phenyl ring. There are two extra methyl groups on the phenyl ring of the reference while claims 2 and 3 of the current invention teach a monosubstituted phenyl. See column 15, line 52, of the reference. Column 3, line 6, indicates a monosubstituted phenyl can be alternatively used and is equivalent to trisubstituted phenyl.

Alternatively, the prior art compounds are homologs. Since a methyl group is considered a homolog of hydrogen these compounds are considered equivalent. The MPEP 2144.09 states "Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH2- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

An additional species renders the claims obvious. A species in column 24, table 1, line 37, provides a compound with two different additional methyl groups, one additional substitution on the phenyl ring and one at R6. The reference teaches the equivalency of the substitution of a methyl and hydrogen at R6. See column 2, line 51. Also, as a second point, the same argument given above for the homology of methyl and hydrogen applies to this situation.

With regards to claim 6, a specie shown in column 36, line 16, where a disubstituted phenyl and R6= methyl is provided. The same scenario as that given above can be used again. The reference teaches the equivalency of a methyl and hydrogen for R6 and a monosubstituted versus a disubstituted phenyl, see above. Also, the homology argument applies to both situations.

Claims 21and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roth et. al (see above for reference).

The current invention teaches substituted pyrrolopyrimidines of Applicants formula (I) and compositions wherein the mixtures contain the active ingredient of formula (I) and one or more other active ingredient, e.g. leukotriene inhibitors, COX inhibitors, glucocorticoids and/or platelet activating factor antagonists, just to name a few. See claim 21, page 14-18. The Specification, page 29, second paragraph, states "asthma of whatever type... chronic or acute bronchoconstriction", as a preferable treatment or prevention of the many diseases listed. Also disclosed in the Specification on page 34, fourth paragraph is the following, "In particular, compounds of the formula (I) are useful in the treatment (1) inflammatory diseases and conditions...".

Roth et. al. teaches compounds of formula (I) and compositions thereof for the treatment of CNS illnesses and inflammations. In columns 5 and 6 (bridged) of said reference Roth acknowledges the combination of compounds of formula (I) with other pharmaceutically active ingredients. Since Roths compounds are used for inflammation it would be obvious for this extra active ingredient to also be anti-inflammatory. The rejected claims include known inflammatory agents e.g. leukotriene inhibitors, which are used to treat asthma, allergic reactions and to sustain inflammation; cox inhibitors, which are a nonsteroidal anti-inflammatory agent; glucocorticoids, which are steroid hormones with potent anti-inflammatory and immunosuppressive properties; and platelet- activating factors, which are potent phospholipids activators and mediators of many leucocyte functions, including platelet aggregation, inflammation, and anaphylaxis. They are also

important mediators of bronchoconstriction. And so it would be obvious to use any anti-inflammatory agent for the treatment of any inflammatory illness, e.g. asthma.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compositions using the teachings of Roth et. al. and expect resulting compositions to contain the uses taught by the art in view of the equivalency teaching outlined above.

Claims 21and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Missbach et. al (see above for reference).

The current invention teaches substituted pyrrolopyrimidines of formula (I) and compositions wherein the mixtures contain the active ingredient of formula (I) and one or more other active ingredient, e.g. transforming growth factors (TGFβ), platelet derived growth factor (PDGF) and MAP kinases. See claim 21, page 14-18. TGFβ are serine / threonine kinase receptors which have been shown, when overexpressed, to cause fibrosis. PDGF exists as five isoforms, which have been linked to fibrosis among other diseases. MAP kinases are serine / threonine specific proein kinases which are involved in various cellular activity, including stimulation of growth factors. On page 32 of Applicants Specification, it states, "... diffuse interstitial pulmonary fibrosis or interstitial lung fibrosis, idiopathic pulmonary fibrosis, cystic fibrosis, ..." as methods of use for the treatment of said diseases.

Missbach et. al. teaches compounds of formula (I) and compositions thereof for the treatment of fibrosis. In column 5, line 1 of the reference Missbach states, "...fibrosis...". Since Missbachs compounds treat fibrosis, it would be obvious include a second fibrosis agent to further enhance the response for the treatment of any fibrosis diseases.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compositions using the teachings of Missbach et. al. and expect resulting compositions to posses the uses taught by the art in view of the equivalency teaching outlined above.

Information Disclosure Statement

The information disclosure statement filed June 23, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered, except for the U.S. patents.

Conclusions

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susanna Moore whose telephone number is (571) 272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SM

Mark L. Berch
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